# Type-II generalized family-wise error rate formulas with application to sample size determination



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| Résumé en anglais | Multiple endpoints are increasingly used in clinical trials. The significance of some of these clinical trials is established if at least r null hypotheses are rejected among m that are simultaneously tested. The usual approach in multiple hypothesis testing is to control the family-wise error rate, which is defined as the probability that at least one type-I error is made. More recently, the q-generalized family-wise error rate has been introduced to control the probability of making at least q false rejections. For procedures controlling this global type-I error rate, we define a type-II r-generalized family-wise error rate, which is directly related to the r-power defined as the probability of rejecting at least r false null hypotheses. We obtain very general power formulas that can be used to compute the sample size for single-step and step-wise procedures. These are implemented in our R package rPowerSampleSize available on the CRAN, making them directly available to end users. Complexities of the formulas are presented to gain insight into computation time issues. Comparison with Monte Carlo strategy is also presented. We compute sample sizes for two clinical trials involving multiple endpoints: one designed to investigate the effectiveness of a drug against acute heart failure and the other for the immunogenicity of a vaccine strategy against pneumococcus. Copyright © 2016 John Wiley & Sons, Ltd. |
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